

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

19 FEDERAL REPUBLIC
OF GERMANY

12 UNEXAMINED
APPLICATION

11 DE 34 02 573 A1

51 Intl.
Classification
A 61 M 25/00
A 61 M 29/00

(Seal)

GERMAN PATENT
OFFICE

21 Application number: P 34 02 573.1
22 Application date: 1/26/84
43 Date laid open to public inspection: 8/22/85

71 Applicant:

Schubert, Werner, M.D., 4330
Mullheim, DE

61: Addition to: P 33 26 648.4

72 Inventor:

Same as applicant

54 Balloon dilation device with cutting tool on a primarily single-lumen multipurpose catheter

The two-lumen Gruntzig balloon catheter is presently held to be the most effective catheter, and it is often preferred for important percutaneous transluminal angioplasty of medium-grade arteriosclerotic coronary arteries.

To contrastingly improve the catheter according to patent claims 1-18, a primarily single-lumen multipurpose catheter is also used with balloon(s). The otherwise single balloon is usefully divided into three parts as has a cutting tool on the sections of the single balloon that runs in a lengthwise direction like the balloon, and the cutting tool also lies on the relatively strong-walled and non-compressing catheter through lengthwise slots. The single-lumen multipurpose catheter is based on P 3326648.4 by Dr. Schubert.

To seal the front nozzle, long auxiliary instruments can be used such as cannulas.

This multipurpose catheter can be used as a guide catheter by inserting preshaped spirals proximally connected to a non-twisting retention wire that can be pressed. The front nozzle body can also contain several nozzles so that other pathways for various functions can be used in the multipurpose catheter. A special catheter with a balloon and cutting tool to eliminate urethral strictures is also presented

Patent claims:

1. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter to cut open internal pathways in the body and primarily to gently open and expand pathway restrictions of various kinds such as arteriosclerotic vascular stenosis, to expand the exit of the large biliary duct into the intestine, to eliminate urethral strictures, etc., characterized in that the elastic balloon (2) to the outside and front of the catheter/probe is divided into several sectors; each of these balloons of equivalent size (2) has small individual knives (1a, 1b) on its humped part that are segmented lengthwise in relation to the catheter whose base is fixed in a recessed, lengthwise plate (3), and the plate (3) consists of hard rubber or the like and is sealed against fluid and connected at the side to the elastic balloon sheath; the sides of the base of the individual knives (1a, 1b) are anchored for restraint via threads (4) to several lateral parts of the catheter wall (6) inside of the balloon (2); the cutting tool (1) together with the knives and balloon (2) is made to protrude for cutting by means of fluid from a proximal direction beyond the lumen of the catheter.

2. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claim 1, characterized in that the elastic balloon(s) (2) on the catheter or probe run lengthwise around the catheter and are elastically pretensioned in the catheter to save space, and the cutting tool (1) with the recessed plate (3) is preferably partially or completely in lengthwise slots (5) of the non-compressing catheter wall (6), and the slots (5) allow fluid to enter the balloon(s) (2) and increasingly dilate the sheath, and the cutting tool (1) on the hump of the balloon (2) is projected outward and runs lengthwise to guide cutting.

3. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-2, characterized in that the pretensioning of the balloon sheath preferably consisting of rubber is supported by a vacuum generated in the catheter/probe, and this vacuum directly and continuously draws the base plate with the cutting tool (1) through the slots (5) in the catheter wall (6) to save space.

4. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-3, characterized in that the cutting tool (1) is longitudinally segmented and designed so that tissue is uniformly cut; this is attained in that the alternating individual knives (1a, 1b) are square (1a) with proximal and distal points on the blades, surrounded above and below by knives with a rounded, oval blade shape (1b), and the entire row of knives (1a, 1b) with closely neighboring blades lie lengthwise on a recessed plate (3) that is comparatively harder than the elastic balloon sheath.

5. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-4, characterized in that the base of the individual knives (1a, 1b) with alternating shapes and blades equal in height are fixed to the trough-like plate (3) cited in claim 2 that runs lengthwise in the catheter, and the plate is made of a hard, rubber-like substance but not solid plastic or the like.

6. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-5, characterized in that the knife-bearing trough-shaped plate (3) made of a solid substance cited in Fig. 2 and 3 is sealed against fluid seated in the much more elastic rubber sheath of the balloon(s) (2), and the plate can be made of a substance other than natural rubber.

7. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-6, characterized in that the knife device (1) is restrained together with the cited knives (1a, 1b) and the humps of the balloon(s) (2) by means of threads (4), and the knives are simultaneously aligned to have the proper angle radial to the axis of the probe/catheter, whereby the threads (4) grip the side of the base of the knives (1a, 1b), and the same threads (4) are anchored laterally inside the balloon(s) (2) in a segmented fashion to the outer wall (6) of the catheter.

8. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-7, characterized in that lengthwise slots (5) are in the balloon catheter wall (6) at the same height, whereby these slots are primarily to receive the recessed plate (3) with the cutting tool (1), and fluid flows through the slots (5) into the balloon(s) (2) to expand the balloon(s) and simultaneously move the recessed plate (3) bearing the cutting tool (1) until the strings (4) tighten to guide the cutting.

9. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-8, characterized in that three balloons (2) corresponding to Fig. 1 are preferably used whereby each has a recessed plate (3) and cutting tool (1), and the balloons are located above the associated lengthwise slots (5) of the catheter, the probe or other long medical instrument, and balloons (2) of this type can lie in a row in penetrations of the catheter wall slots (5).

10. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-9, characterized in that the used catheter has a movable front nozzle (7) according to patent application P 33 26 648.4 by Dr. W. Schubert in Fig. 5, 6, 9, 10, 12, 13 and 14 whose front nozzle can be sealed

by a conical seal on a retention wire (8) or, in a novel feature, by auxiliary instruments such as cannulas (10a, 16a, and 16b), and the front nozzle body contains several nozzles with unequal widths that can be sealed as mentioned above with different auxiliary instruments which allows different activities to be carried out simultaneously in a televised operation such as aspiration or drainage.

11. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-10, characterized in that very large lengthwise balloons with cutting tools (11) are in the front of the catheter or probe over lengthwise, partially interrupted slots (5) in the catheter wall (6) that the balloons cover so that stenoses several centimeters long can be expanded in one session by using catheters with a movable front nozzle (7) as especially shown in Fig. (8).
12. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-11, characterized in that the catheter is a special catheter with a balloon(s) (2) and cutting tool (1) to eliminate urethral strictures (Fig. 6) with a strongly narrowing front part of the catheter; the front of this special catheter has another olive-shaped, small, rather solid and slightly expandable front balloon (9) with a very narrow front nozzle (7a) for fluid, with a second pathway as a cannula (10) for lubricant that runs the entire lumen of the special catheter that is otherwise constructed to eliminate urethral strictures according to the principle in Fig. 1-4, but it is not as long as a heart catheter.
13. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-12, characterized in that one or more cannulas (16a, 16b) are advanced through the front nozzle(s) (7, 7b, 7c) within the lumen of the bodily pathway to the front of the catheter for injection, aspiration, blood pressure measurement, etc. and such a cannula (10a) with a relatively wide nozzle can be used to advance a small elastic balloon as the front balloon far to the front as shown in Fig. 8.
14. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-13, characterized in that the knives (1a, 1b) in the balloon sheath (2) or the recessed plate (3) are also made of plastic and still have sharp enough blades so that they can be made in a single casting with the plate (3).
15. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-14, characterized in that the blade is primarily in the form of a single wire with a flat base to receive

or affix the recessed plate (3), whereby the cutting device follows a lengthwise, serpentine line and only cuts to the outside when the balloon is dilated.

16. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-15, characterized in that the guide catheter is passive as it adapts to the given pathway curvatures of the body in that one or several sequential correspondingly preshaped spiral springs made of steel or another substance is advanced in the relatively wide lumen of the multipurpose catheter and compressed against the front nozzle, and the front part of the multipurpose catheter largely adopts the shape of the preshaped spiral.

17. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-16, characterized in that the preshaped spiral (13) is proximally connected to a non-compressing and non-twisting retention wire, and the rear of the wire has a knob for rotating the (steel) wire (spiral).

18. Balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter according to claims 1-17, characterized in that the proximal seal (20) that seals against fluid consists of rubber sleeve (19) whose inner diameter corresponds to the diameter of the auxiliary instrument inserted in the multipurpose catheter; the sheath-like inside of the proximal part of the catheter wall can be place against this rubber sleeve, and the rear of the catheter can be pressed tightly against the entire perimeter of the rubber sleeve (19) to seal it using a clip with a screw (21).

INSTITUTE FOR PATHOLOGY
W. SCHUBERT, M.D., PATHOLOGIST

To:
German Patent Office
Zweibrückenstr. 12
8000 Munich 2

4330 Mulheim (Ruhr)
Dohne 32 – Tel.: (02 08) 3 37 40
Essen postal checking account: 1266 43 439
Commerzbank Mulheim (Ruhr)
(Bank routing No.: 362 400 45), account No. 7 741 457
Date: 1/20/84

Balloon Dilation Device with a Cutting Tool on a Primarily Single Lumen Multipurpose Catheter

The invention concerns a balloon dilation device with a cutting tool on a primarily single-lumen multipurpose catheter to cut open internal pathways in the body and simultaneously to gently open and expand pathways restrictions of various kinds such as arteriosclerotic vascular stenosis, to expand the exit of the large biliary duct into the intestine, to eliminate urethral strictures, etc. for efficient medical teleoperations that are gentle to the patient.

When using such balloons at the front of a probe, catheter or other long medial instrument, a cutting tool is required on the balloon, for example in the time-tested operation of creating stretch and tear lines by cutting the perineum during birth. This is done e.g. in the vascular system by only cutting the inner tissue layers lengthwise using the device cited in patent claim 1. This allows the inner layers to stretch more in comparison to the outer wall layers so the vessel can expand while retaining the important outer wall layers and preventing local, secondary hazardous wall tearing in the area of the stenosis.

In the case of endoscopic papillotomy, pure mechanical expansion is used where a wire is heated red hot with electricity to eliminate the restriction of the biliary duct exit by cutting the inner tissue layers.

In another very new procedure (as related personally by a physician), a balloon catheter is used to expand the papilla (also without a cutting tool).

Urologists have recently had success in mechanically expanding the urethra to eliminate strictures by means of a very useful, long cutting tool. This procedure involving the lengthwise cutting of the strictures with a knife, termed internal urethrotomy, is clearly superior to electrical cutting or mere dilation.

Publications concerning Grüntzig balloon catheters are attached: Andreas R. Grüntzig et al.: "Transluminale Coronardilatation – Bestandsaufnahme und Ausblick" [Transluminal Coronary Dilation – Opinion and Outlook], Deutsches Ärzteblatt, Vol. 80, No 38, September 23, 1983; Gisbert Kober: "Die neue Behandlungsmethode: Ballondilatation" [The New Treatment Method: Balloon Dilation], Zeitschrift der deutschen Herzstiftung, 6000 Frankfurt am Main, Special print from No. 3, 1983. These Grüntzig catheters are two-lumen with a single balloon in which contrast medium can be introduced through the narrow second lumen.

There is no prior-art cutting tool on such a balloon, and Grüntzig has not published one. A disadvantage in this world-renowned procedure especially for percutaneous transluminal coronary dilation is the usually high pressure that must be used in angioplasty up to 13 atmospheres which was discussed in the patent by W. Schubert, M.D., 33 26 648.4: "Catheters with Adjustable Front Nozzle and a Balloon". The higher the pressure, the more difficult it is to avoid sizable vascular wall tearing.

Even Grüntzig feels that methodological refinement is necessary.

For the pathways of the body, there needs to be dilation devices that act on a greater area for the trunks of the coronary arteries restricted by arteriosclerosis, and for more strongly kinked neck arteries, pelvic, leg and other arteries constricted by arteriosclerosis.

An expanding device that covers a wider area and a cutting tool are disclosed in the patent claims according to the invention and illustrated in Fig. 5, 6 and 8. In addition, we present for the first time a multipurpose catheter with additional important functions and a special catheter to remove urethral strictures, which is generally quite difficult. This multipurpose catheter present by us for the first time can be easily and quickly transformed into a two-lumen catheter in which an additional cannula is introduced through the main lumen up to the front nozzle for aspiration and injection. A guide wire can also be introduced through the multiuse catheter for conventional functions. The front nozzle can now be sealed, and sealing the rear of the multipurpose catheter should no longer be difficult. We above all hope that the percutaneous transluminal use of this multifaceted multipurpose catheter can reduce the number of serious operations such as bypass operations involving an open chest cavity.

The invention is based on the problem of gently and safely alleviating various kinds of stenoses, especially the numerous arterial stenoses such as coronary artery stenosis, neck artery stenosis, urethral strictures, etc.

especially by the use of our disclosed multipurpose catheter.

This problem is solved according to the invention in that a cutting tool (1, 1a, 1b, 1c) that runs in the lengthwise direction of the catheter or probe is inserted in the balloon sheath (2), and it lies protected from fluid at the height of the catheter wall in lengthwise slots (5) in the relatively strong wall (6) of the single-lumen multipurpose catheter. The balloon is expanded proximally from the outside thorough the catheter by means of fluid, and the cited slots (5) provide substantial space for the passage of fluid.

With the relatively wide uniform lumen of the multipurpose catheter, large balloons that extend rather far in a proximal direction can be used, e.g. to dilate constricted coronary artery trunks in one session with the use of the cutting tool (1) to cut open the hardened and morbidly thickened inner layers of the vascular wall.

Projecting arteriosclerotic plaque is more efficiently cut open by the lengthwise series of knives.

To ensure flexibility of the multipurpose catheter, the cutting tools (1) inserted in the balloon were divided into segments of individual knives (1a, 1b) as shown in Fig. 2 and 3. They consist of square blades (1a) that alternate with knives with ovular blades (1b). The bases of the individual knives (1a, 1b) are fixed in an approximately trough-shaped plate (3). The plate (3) is made of hard rubber, plastic, or a similar material and is harder than the actual balloon sheath (2).

A single, serpentine, more wire-like cutting device (1c) can be placed in the recessed plate with its base fixed to the plate (Fig. 4). When the balloon expands, the knife is projected and becomes linear running in a lengthwise direction in relation to the catheter.

Another possible cutting device in a recessed, hard plate (3) is a longitudinal, serpentine bead of hard rubber, etc. with numerous lengthwise cutting devices (1) affixed to the plate, some of which can be initially adjacent. As the inside of the balloon sheath (2) expands, a largely uniform, strongly projecting blade is created (Fig. 4a).

Retention threads (4) inside the balloon(s) (2) can also restrain the lengthwise cutting tool (1) on the catheter. On the one hand, they hold the base of the knives (1a, 1b), and lead from inside the balloon (2) to several lateral, outer parts of the catheter wall (6) where they are anchored next to the slots. These retention threads (4) can also move the knives (1a, 1b) radially into a good cutting position in relation to the stenosis under the effect of fluid when the balloon (2) expands and prevent the elastic balloon (2) from over-expanding.

For reasons of fluid dynamics, it is useful to affix three balloons (2) with cutting tools (1) to such catheters; we do not yet have experience with a prototype.

In another insightful version, the preliminary tension of the elastic balloon(s) (2) is set so that the balloon (2) can evenly expand, and the cutting tools (1) are recessed in slots (5) of the catheter to save space. The elastic, individual balloon preferably consisting of natural rubber with the plate and (3) and cutting tool (1) lies tightly against the catheter wall under its own tension. This manner of affixing the balloon to the catheter to save space is more advantageous than Grüntzig's balloon catheter whose unretractable plastic balloon projects rather far from the catheter shaft.

If contrast medium is to be injected, the blood pressure is to be measured, or a guide wire is to be inserted using the multipurpose catheter described in the patent claims, a frontal nozzle (7) is necessary in addition to the balloon(s) (2), and it must be adjustable as mentioned in the German patent 33 26 648 by Dr. W. Schubert.

However, in regard to the multipurpose catheter, the front part of the probe or catheter can have a supplementary nozzle body with several nozzles that in this case all face the front and of course can be sealed (Fig. 14). The nozzle body has a narrow and wide nozzle (7b, 7c). An endoscope can be advanced through the wider nozzle (7c), for example. If such auxiliary instruments such as cannulas seal the associated nozzle, balloon(s) or other items on the side of the catheter can be filled with fluid.

The catheter that we have created can therefore be used in many applications. Instead of just a sealing cone with a retention wire (8) to provide a seal (Fig. 6), conically narrowing cannulas (Fig. 9) that act as a valve, or long, continuous cannulas (Fig. 10) can be used; even a narrow endoscope could be additionally advanced through the catheter. The rear edges of the respective nozzles should be rounded so that the instruments can more easily slide through.

In regard to special catheters for eliminating urethral strictures, the particular anatomy of male urethras must be taken into consideration. The tender mucous membrane easily yields in the soft, spongy environment. Some of such urethral strictures are arachnoidal with fine gaps or residual lumina that must be looked for in a delicate and cautious manner. Initial points of attack only arise after the residual lumina at the front of the catheter have been passed through. The front part of this special catheter must be very narrow (Fig. 7). In the same figure, a

very small, hard balloon (9) that only expands slightly is on the front of the catheter with a very fine front nozzle (7a) so that fluid with lubricant can exit to expand the residual lumen in the area of the stricture by means of fluid as much as possible and thereby insert the thin front part of the catheter into this opening, advance it enough so that the blades on the balloon can be used to eliminate the stricture, and the balloon (9) can also be used to expand the stricture.

If the cannula (10a) shoved through the front nozzle (that can consist of conventional, highly flexible, metal that does not easily deform) has an outer diameter that is not quite as large as the diameter of the front nozzle, the front nozzle can function as a valve, i.e., the cannula can seal the front nozzle.

One of the most important functions of the multipurpose catheter should be that of a guide catheter. It can be used to reach the right location for teleoperations in a manner that is gentle for the patient. Fig. 12 and 13 show a device that is not prior art which uses preshaped spinal springs. There is a desirable deviation from a straight line whereby the catheter is deformed inside the bodily pathway adapted to the anatomy by inserting such a preshaped spinal spring connected to a non-twisting wire (14) at the proximal end (conventional x-ray monitoring is often required). In this manner, proximal (i.e. outside the body) three-dimensional changes in the catheter or probe shape can be made at the front of the catheter. In addition, the catheter can be proximally advanced or retracted. Part of this technique involves pressing the preshaped spinal spring (13) to the front inside the catheter so that the spiral is relatively straight. Only when the spinal retention wire (14) is released at the proximal end does the spiral spring expand, and the catheter assumes the spiral's predetermined bent shape.

Building on patent 33 26 648.4, we show another simplified version of the proximal seal of the multipurpose catheter in Fig. 9. Between the outer wall of the cannula (16a) and the inner wall of the multipurpose catheter, a rubber sleeve is placed to provide a seal (19) against fluid. On the outside of the rear of the catheter is a clip with a screw to seal the rubber sleeve with enough pressure.

Substantial Advantages of the Invention

a) A lengthwise knife on the hump of the balloon (initially recessed in slots of the catheter wall) can make long cuts gently in hardened and thick inner wall layers of frequently-occurring arteriosclerotic stenoses in teleoperations by applying fluid pressure.

b) The elastic balloon in Fig. 1,2 saves space in relation to a plastic balloon, especially when the lengthwise knife with the recessed plate is also in the lengthwise slot of the probe. The balloon in the Grüntzig catheter contrastingly consist of a non-elastic, membranous, transparent plastic material.

c) The manufactured single-lumen multipurpose catheter in claims 1-18 has a substantially stronger shaft in comparison to the Grüntzig catheter which of course does not restrict the front part from greatly narrowing with a relatively uniform, wide lumen. This allows lengthwise, penetrating slots in the catheter wall for the passage of fluid as is desirable when the balloon expands.

d) Given the relatively large penetrations for fluid in the catheter wall and the generally wide passage for fluid from a proximal direction, the precise internal pressure of the balloon can be measured externally with a sensitive manometer. It is hence to be expected that medium-grade coronary arteries that may be greatly deformed with arteriosclerosis can be substantially expanded with less than 1 atmosphere, especially since the inner layers are slit lengthwise.

e) As can be seen in Fig. 8 in particular, substantially larger balloons can be placed on the catheter or probe with the cutting tool where the balloon is divided into three or more parts so that entire vascular trunks of the cardiac arteries can be expanded in a single session in a teleoperation which is less invasive than bypass operations where the chest cavity is opened.

f) The urethral stricture catheter in Fig. 7 shows axial auxiliary cannulas with a fine balloon and a very fine front nozzle (10, 9, 7a). By means of this fine front device, very fine residual openings in the urethra can be found, penetrated with lubricant and the cicatricial, sometimes arachnoidal structural changes can be eliminated with a balloon and the cutting device. We are aware of no prior-art balloon with a cutting tool. The entire device in Fig. 7 with the tool should be gentler even with fluid than conventional devices.

g) We are unaware of any prior-art catheter that is justifiably called a multipurpose catheter. The Grüntzig balloon catheter is held to be the most advanced catheter and is a two-lumen catheter. The single lumen multipurpose catheter according to the invention is also a two-lumen catheter especially given the above-cited advantages when a suitable cannula is advanced from a proximal direction into the front nozzle to seal it.

h) Other cannulas can be inserted in the multipurpose catheter in the primary relatively wide uniform lumen

(Fig. 14). The front nozzle body can also have several nozzles of different sizes for cannulas of different widths. Even a narrow endoscope can be advanced through a wide nozzle. With such artificial pathways in the multipurpose catheter, there is still enough room in the main lumen to introduce sufficient fluid in the expanding balloon.

i) Since the wall of the multipurpose catheter is relatively stiff, a higher vacuum in all probability functions better for aspiration than in the Grüntzig catheter.

j) We are unaware of the prior-art use of preshaped spiral springs in catheters. A relatively wide, uniform lumen is required which is not offered by the Grüntzig catheter. The catheter wall must be very solid. A nozzle body to reinforce the front part (15) of the catheter is also necessary as in our multipurpose catheter (see Fig. 5, 6, 9, 10, 12, 13 and 14). The spiral spring cannot be pressed out of the front of the catheter into the pathway of the body. In this manner, the front of the catheter can be bent or guided in a three-dimensional manner in a teleoperation from outside the body using a spiral retention wire. Also given the rigidity of the catheter wall in connection with the spiral retention wire, the front of the catheter can be advanced, or the catheter can be withdrawn. Even when the spiral is inserted, injections and aspiration can be carried out from outside using such a multipurpose catheter.

Drawings:

Fig. 1 is a cross-section of a probe or catheter or another long medical instrument with a three-part balloon (2) placed over long slots (5) in the catheter wall (6). The slot(s) (5) are covered by the balloon (2) and sealed against fluid. The individual cutting tools (1) are in a recessed plate (3) consisting of a hard-rubber-like or plastic-like substance. By means of fluid pressure, this plate (3) with the cutting tool (1) can be pressed outward, and the elastic balloon is expanded (Fig. 1 and 5). The plate (3) with the cutting tool (1) and other parts of the elastic balloon are restrained by strings (4) that grip the side of the base of the individual knives (1a, 1b) and are anchored to the side in the balloon(s) (2) to the catheter wall.

Fig. 2 shows a side view of individual cutting tools (1) in a vertical row. The blades overlap to suitably guide the cutting; this is achieved with square knives with protruding blades at the side (1a) and neighboring blades that are more ovular (1b). These alternating individual knives (1a, 1b) have blades that have different shapes, and their base is fixed to the recessed plate (3) cited in the description of Fig. 1. Such knives can be vulcanized to the plate (3).

Fig. 3 shows a view of such knives (1a, 1b) that are affixed in the recessed plate (3).

Fig. 4 shows a serpentine wire or wire-like structure (1c) that changes into a blade that can be solid plastic with a blade affixed in the recessed plate (3).

Fig. 4a shows a corresponding lengthwise serpentine bead on the recessed plate (3) in the catheter. The bead has numerous lengthwise blades, some of which are adjacent. After pressure from fluid is applied and the balloon (2) expands, the serpentine structure with the knives affixed in the recessed plate (3) stretches as in Fig. 4 so that the numerous fine individual knives form a row, protrude and assist cutting.

Fig. 5 shows the lengthwise cut in the front of a single-lumen catheter which we have termed a multipurpose catheter due to the variety of its uses. The frontal nozzle (7) is not sealed by a valve. Injections are possible, and material from the pathway of the body can be aspirated. The inflatable balloon (2) is contracted with the recessed plate (3) that is completely or partially in the lengthwise slot (5) in the relatively strong catheter wall (6) to save space. The recessed plate (3) bears the cutting tool (1) that also runs lengthwise in reference to the catheter. The cutting tool is divided into numerous segments with a shape corresponding to individual knives

(1a, 1b).

Fig. 6 shows a lengthwise section of the same multipurpose catheter as in Fig. 5 but with a front nozzle (7) sealed by a conical valve (8) advanced by the retention wire inside the catheter.

When the balloon (2) with the cutting tool (1) is filled with fluid and projects outward lengthwise in reference to the catheter, it can cut bodily pathways by pressing against the inner wall layers.

Fig. 7 shows the special catheter for eliminating urethral strictures. This catheter is designed as a two-lumen catheter and bears two balloons (2,9). The small, slightly inflatable front balloon (9) has a very fine nozzle (7a) at the front. Liquid with lubricant can be injected from within the catheter lumen via cannulas (10) through the nozzle into the urethra to locate residual urethral lumina in front of the catheter. When lubrication passes through the stricture, fluid expands the balloon (2) via the main lumen of the catheter and extends several lengthwise cutting tools (11). The catheter wall (6) must be relatively strong so as not to compress.

Fig. 8 shows a lengthwise section of the above-cited multipurpose catheter. The balloon with its associated cutting tool (11) that runs in a lengthwise direction in relation to the catheter is substantially larger in comparison to Fig. 1, 5 and 6. With such a large balloon, coronary artery trunks that have been restricted and thickened by arteriosclerosis can be expanded. The front nozzle (7) is sealed by a cannula (10a) advanced from a proximal direction through the entire catheter. A very thin-walled elastic balloon (9a) was introduced into the lumen of this cannula toward the front, and the balloon was inserted into the pathway of the body by means of fluid and expanded. The basically non-compressing catheter wall is identified with the number 6.

Fig. 9 shows a lengthwise section of the multipurpose catheter with a front nozzle (7) that is sealed by the long cannula (16a). A special feature of the front of this large-lumen cannula is that its front narrows to precisely the width of the front nozzle. The cannula cannot therefore be shoved out beyond the distal end of the front nozzle (7) into the bodily pathway. 6 again represents the relatively non-compressing and pressure-resistant catheter wall. Connectors for pressure and vacuum are identified with 17 for which at least one valve (12) is necessary. The rear seal (20) of this multipurpose catheter consists of a lengthwise rubber sleeve that surrounds the introduced cannula (16a), and a sealing clip with a screw (21). The rear of the cannula (16a) can also have a connector (18).

And Fig. 10 shows a lengthwise section of the front part of such a multipurpose catheter with a front nozzle (7). A relatively narrow-lumen cannula or similar tubular structure (16b) extends through the front nozzle far into the bodily pathway. 6 again identifies the relatively compression and pressure-resistant wall of the catheter.

Fig. 11 shows a preshaped spiral (13) made above all of high-grade steel whose diameter is somewhat smaller than the lumen of the still-straight catheter shown in Fig. 12 with a front nozzle (7) and wall (6). The back of this previously L-shaped spiral spring (13) is connected to a to rather non-compressing and non-rotating retention wire (14).

Fig. 13 shows the same catheter that is straight in Fig. 12; however, the front of the catheter is clearly bent to the side by the spiral spring (13) preshaped at a right angle. Material can be injected and aspirated through the front nozzle (7) in this state as well which reinforces the term "multipurpose catheter".

Fig. 14 shows a lengthwise section through the front part of such a multipurpose catheter with a front nozzle in the body (15). This front nozzle in the body contains at least two nozzles with different widths: a wide-lumen nozzle (7c) that could be suitable for receiving a very narrow endoscope, and an adjacent, narrow-lumen second nozzle (7b) for cannulas or other devices that can act as a valve, whereby the balloon(s) (2) can also be expanded in the remaining main lumen of the multipurpose catheter. The inner insertion sites for the nozzles should be rounded so that the advanced auxiliary instruments such as endoscopes, cannula, etc. can find the correct path.

When the nozzles have different widths, the larger instrument is first introduced into the corresponding nozzle (7c), and then the small-caliber instrument is introduced into the narrow-lumen nozzle (7b).

Legend:

- | | | |
|----|----|--|
| 1 | -- | Cutting tool |
| 1a | -- | Square individual knife with a pointed blade |
| 1b | -- | Oval individual knife |
| 1c | -- | Uniform serpentine cutting tool affixed to the recessed plate that stretches to guide cutting when the balloon expands |
| 2 | -- | Balloon divided into three sections on the catheter, or three balloons of equal size on the catheter |
| 3 | -- | Recessed plate for tightly holding the base of the individual knives in rows, and to connect the |

- elastic balloon (2)
- 4 -- Holding strings for the cutting tool (1a, 1b) and the plate (3) anchored to the probe or catheter wall
- 5 -- Lengthwise slots in the probe or catheter wall
- 6 -- Catheter wall or probe wall
- 7 -- Front nozzle
- 7a -- Front nozzle on a smaller, slightly expandable front balloon for a urethral stricture catheter
- 7b -- Narrow-lumen front nozzle
- 7c -- Wide-lumen front nozzle
- 8 -- Retention wire with sealing body
- 9 -- Slightly expanding small front balloon
- 9a -- Front balloon in/on a cannula as auxiliary instrument for catheters with a front nozzle and balloon
- 10 -- Separate fluid tube running in a special catheter that also provides lubricant
- 10b -- Cannula that also serves as a seal for the front nozzle for injecting while expanding a vessel, measuring blood pressure, etc.
- 11 -- Expanding part of the catheter with a balloon(s) and cutting tool from Fig. 1 - 5
- 12 -- Valve in a connector (Fig. 9)
- 13 -- Preshaped spiral with a non-twisting retention wire
- 14 -- Retention wire for preshaped spirals
- 15 -- Front nozzle body with two or more front nozzles (Fig. 14)
- 16a -- Cannula that narrows toward the front and also serves as a valve seal
- 16b -- Cannula that can be advanced far through the front nozzle which also serves as a front valve
- 17 -- Connector for pressure and vacuum
- 18 -- Proximal connector on the cannula
- 19 -- Rubber sleeve
- 20 -- Proximal seal for the primarily single-lumen catheter with a front nozzle
- 21 -- Screw for the proximal sealing clip on the catheter

Nummer: 34 02 573
 Int. Cl. 3: A 61 M 25/00
 Anmeldetag: 26. Januar 1984
 Offenlegungstag: 22. August 1985

3402573

39.

Fig. 4

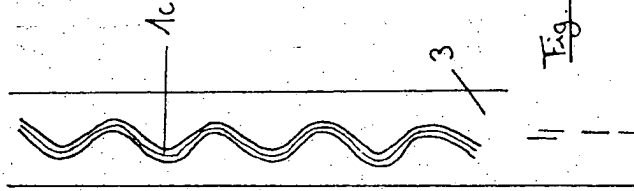


Fig. 4a

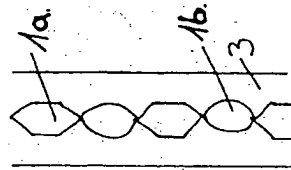
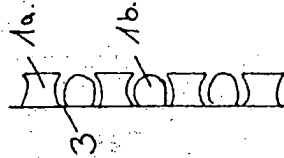


Fig. 2

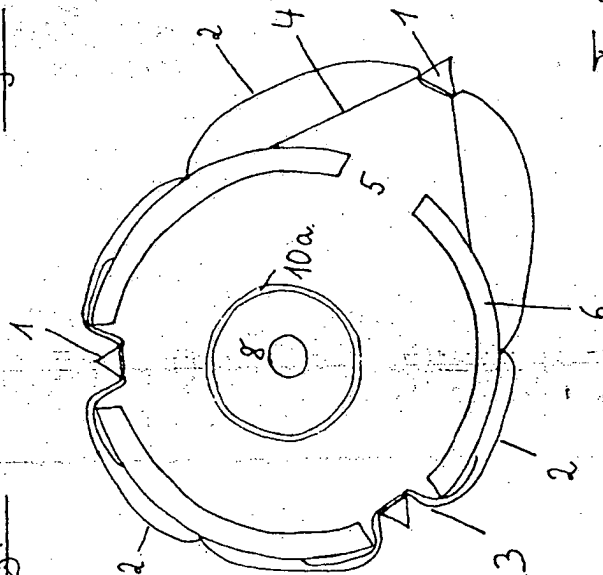
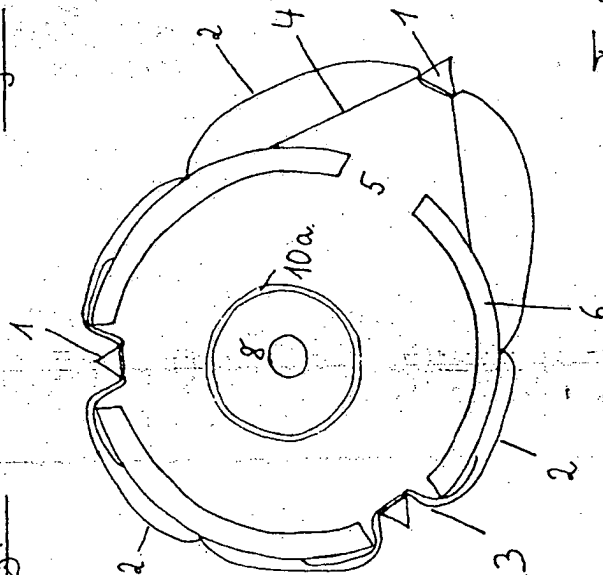


Fig. 3

Fig. 1



3402573

- 35 -

3402573

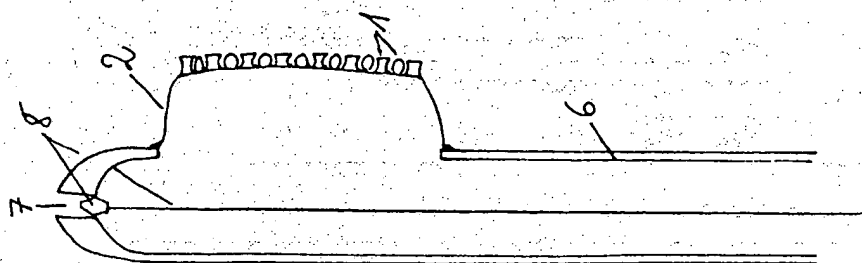


Fig. 6

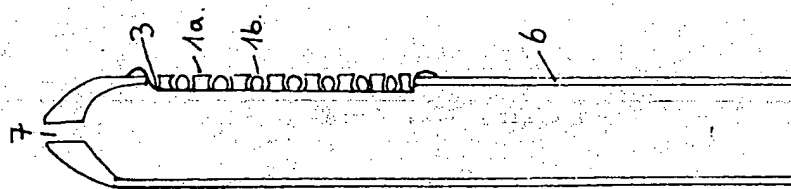


Fig. 5

26-01

3402573

36.

Fig. 7

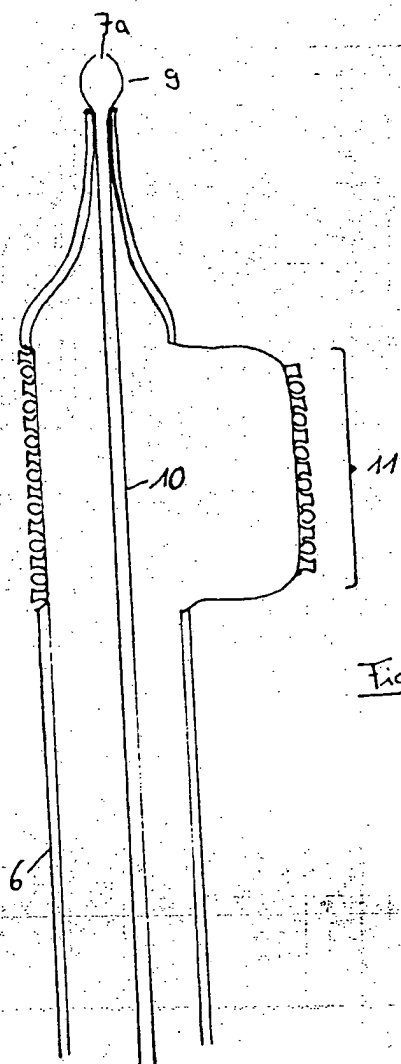
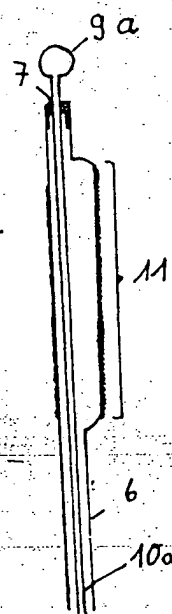


Fig. 8



Harnröhrrenstrikkwren Katheter

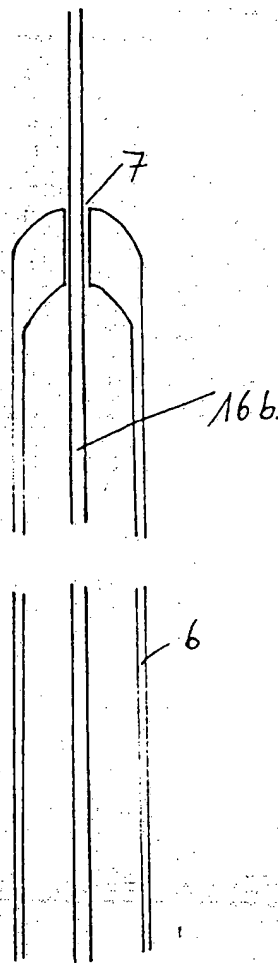
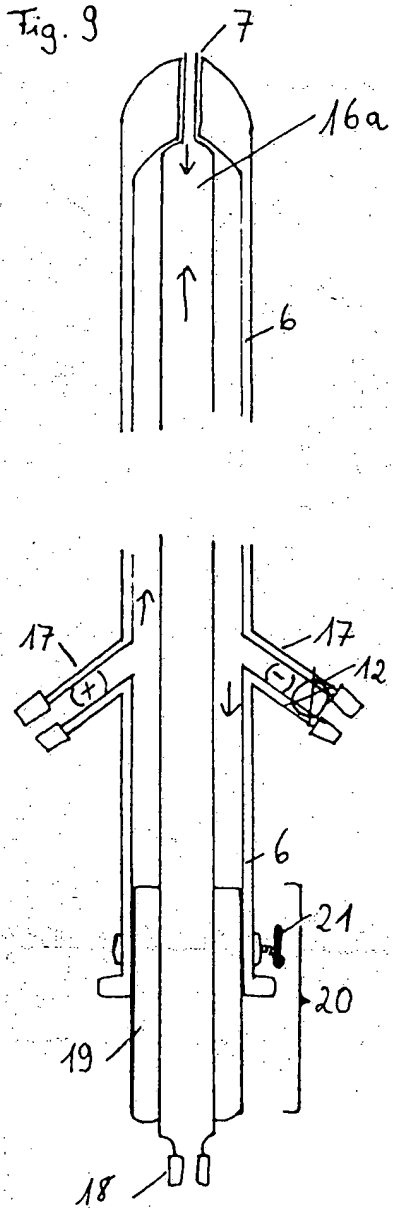
250184

3402573

- 37 -

Fig. 9

Fig. 10



Mehrzweckkatheter

3402573

38

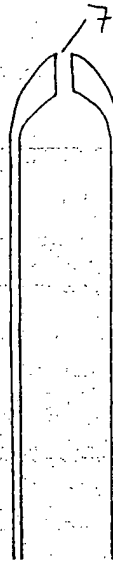


Fig. 12

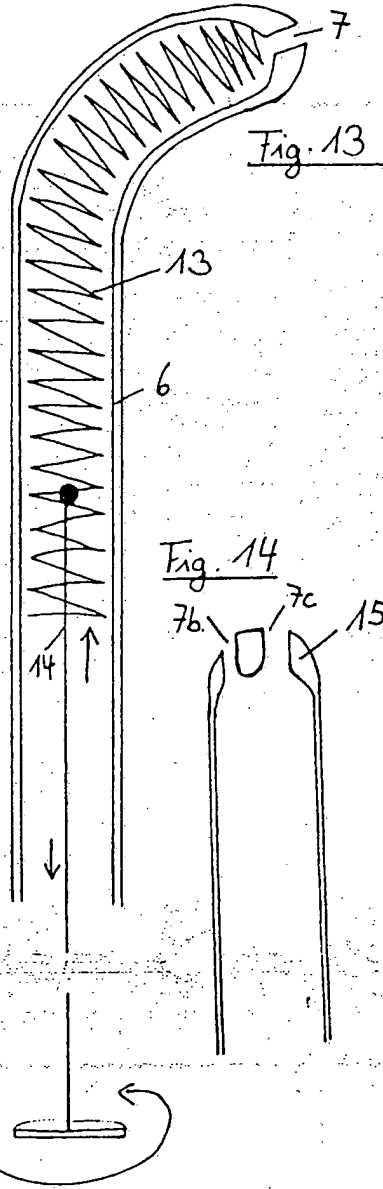


Fig. 13

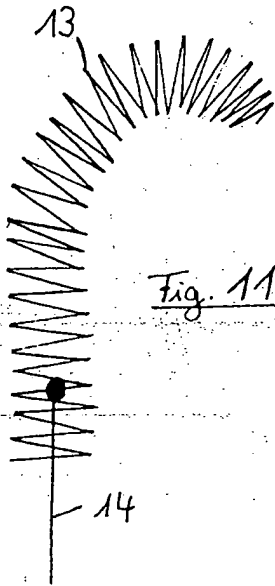
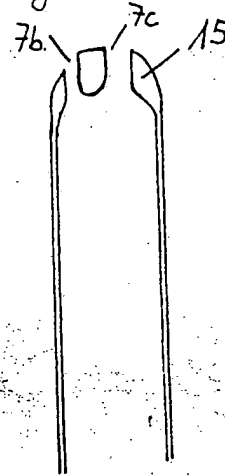


Fig. 11

Fig. 14



THIS PAGE BLANK (USPTO)